

Learning curve for robot-assisted Roux-en-Y gastric bypass

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Abstract

Background Robot-assisted Roux-en-Y gastric bypass (RYGBP) is rapidly evolving as an important surgical approach in the bariatric field. However, the specific learning curve associated with this new approach remains poorly investigated. This study aimed to evaluate the learning curve for robot-assisted RYGBP.

Methods A series of 64 consecutive robot-assisted RYGBP procedures were performed between December 2008 and December 2010 by a single surgeon already experienced in advanced laparoscopic procedures but not in bariatric surgery. All data were collected prospectively in a database and reviewed retrospectively. The learning curve was evaluated using the cumulative sum (CUSUM) method.

Results Women comprised 76.6% and men 23.4% of this series. These patients had a mean age of 43 years and a mean body mass index (BMI) of 44.5 kg/m². The mean operative time (OT) was 238.1 min (range, 150–400 min). A total of six complications occurred (9.4%). The CUSUM learning curve consisted of two distinct phases: phase 1 (the initial 14 cases; mean OT, 288.9 min) and phase 2 (the subsequent cases; mean OT, 223.6 min), which represented the mastery phase, with a decrease in OT ($P = 0.0001$). The two groups were similar in terms of gender, age, and BMI. The two phases did not differ in terms of complications or hospital stay.

Conclusions This series confirms previous study findings concerning the feasibility and the safety of robotic RYGBP even after a limited experience with laparoscopic RYGBP. The data reported in this article suggest that the learning phase for robot-assisted RYGBP can be achieved with 14 cases.

Keywords Complications · CUSUM · Da Vinci · Gastric bypass · Learning curve · Operative · Robotic time

Obesity has become a major health problem in the developed countries. In parallel, laparoscopic Roux-en-Y gastric bypass (RYGBP) has become the most frequently performed bariatric procedure in the United States [1], and the demand for it continues to grow [2]. However, in contrast to the laparoscopic adjustable gastric band, laparoscopic RYGBP remains a technically challenging procedure requiring advanced laparoscopic skills [2, 3]. Moreover, limitations often are associated with standard laparoscopy including ergonomics, two-dimensional vision, tremor, and limited range of motion of the instruments.

Mastery of laparoscopic RYGBP is reported to entail a steep learning curve, during which time the operative time and morbidity rate are increased [2]. At this writing, the learning curve for laparoscopic RYGBP is reported to be 75–100 cases [4–7].

To overcome the limitations of standard laparoscopy, robotics has been developed with three-dimensional view, endowristed instruments offering increased freedom of motion, and a tremor filter. Findings have shown many advanced robotic procedures to be feasible and safe [8–10]. Besides, in the bariatric field, the da Vinci Surgical System (Intuitive, Sunnyvale, CA, USA) is reported to improve ergonomics [2, 11]. Although several groups have

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published encouraging results, notably a reduced anastomotic complications rate compared with laparoscopy [12, 13], clear advantages still are under evaluation. However, the learning curve associated with a robotic approach has been poorly evaluated [2–4]. To the best of our knowledge, no study has used cumulative sum analysis (CUSUM), which transforms raw data into running total data deviations from their group mean, enabling investigators to visualize the data for trends not discernable with other approaches [14]. This study aimed to analyze the initial learning curve for robot-assisted RYGBP using CUSUM methodology.

Materials and methods

Between December 2008 and December 2010, 64 consecutive robot-assisted RYGBP procedures were performed by a single surgeon (F.P.) already experienced in advanced laparoscopic procedures (e.g., colorectal resections, splenectomy, biliary exploration, complex ventral hernia repair). However, his previous experience in laparoscopic RYGBP was limited to 10 cases.

After an initial mentoring of 50 robot-assisted RYGBP cases working as the patient-side surgeon, he started managing his own cases using the same technique in the Department of Surgery at the University Hospital of Geneva, Switzerland. The very initial cases were supervised by one of the mentors (G.C., P.M.) working as the patient-side surgeon. Data were entered prospectively by a research nurse (P.K.F.) into a dedicated bariatric database and retrospectively reviewed.

The patients included in this study met the National Institutes of Health (NIH) consensus criteria [15] for bariatric surgery and fulfilled the institutional guidelines of medically supervised weight loss and psychological clearance. Queries on patient demographics, operative variables, and complications were performed. The operative time (OT) was defined as the time between the first skin incision and the last port closure.

Age, gender, preoperative weight and body mass index (BMI), intra- and postoperative complications (30-day morbidity), and readmission within 30 days after surgery also were evaluated. A complication was defined as any deviation from the normal postoperative course. To classify the severity of the complications, we used the Dindo–Clavien classification [16] consisting of five grades and two subgroups. Patients were followed up in the outpatient clinic.

Surgical technique

All the procedures were performed using the same technique. The intervention started via a laparoscopic approach

with a routine cholecystectomy. The gastric pouch was created using the laparoscopic approach as well.

Then, the da Vinci Surgical System (Intuitive, Sunnyvale, CA, USA) was docked coming from the patient's head. A total of five ports were used in this series. The remainder of the procedure was performed altogether robotically. The gastrojejunostomy (GJ) was performed using a single-layer back and front running suture. A side-to-side jejunojejunostomy (JJ) was performed using the same technique. A closed-suction drain was left routinely posterior to the GJ.

Cumulative sum analysis

Like others [14], we used the CUSUM technique for quantitative assessment of the learning curve. The CUSUM is the running total of differences between the individual data points and the mean of all the data points. The CUSUM was used to assess the OT for all 64 cases.

To calculate the CUSUM, the cases were ordered chronologically. The CUSUM of the first case was the difference between the OT for the first case and the mean OT for all the cases. The CUSUM of the second case was the previous case's CUSUM added to the difference between the OT for the second case and the mean OT for all the cases. The process was continued to the CUSUM for the last case. As in the study by Bokhari et al. [14], risk-adjusted CUSUM was not performed because no deaths occurred in this series.

Statistical analysis

The results of parametric data are expressed as mean \pm standard deviation and the results of nonparametric data as median (range). GraphPad software (GraphPad, La Jolla, CA, USA) was used for all statistical analyses. Confidence intervals were set at 95%. A two-sided *P* value of 0.05 or less was considered statistically significant. Comparisons between groups were performed using Fisher's test for discrete variables and Student's *t* test for continuous variables.

Results

During a study period of 2 years, 64 consecutive robot-assisted RYGBP procedures were performed by the same surgeon. The patients were 49 women (76.6%) and 15 men (23.4%) with a mean age of 43 years (range, 21–63 years). The mean preoperative BMI was 44.5 kg/m² (range, 30.9–59 kg/m²), and the mean preoperative weight was 121.6 kg (range, 80–191.7 kg). The patient with a BMI of 30.9 kg/m² underwent a robot-assisted RYGBP after a

previous laparoscopic adjustable gastric banding. The patient demographics are summarized in Table 1.

The mean OT was 238.1 min (range, 150–400 min). The patient with an OT of 400 min was a man with a BMI of 44 kg/m². He was one of the first cases in this series. No intraoperative complications, conversions, or deaths occurred. The perioperative results are summarized in Table 2.

Six postoperative complications were recorded (30-day morbidity rate, 9.4%). Four complications were grade 2 according to the Dindo–Clavien classification (1 pulmonary embolism, 1 deep venous thrombosis, 1 digestive hemorrhage requiring transfusion, and 1 anastomotic edema at the level of the GJ), and all were treated conservatively with success. One patient experienced an acute internal hernia (grade 3b) with ileus requiring an early reoperation (1.6%) on postoperative day 5. Finally, one patient presented with an atelectasis and severe hypoxemia, necessitating a short stay in the intensive care unit (grade 4a). The mean hospital stay was 6.5 days (range, 3–14 days). The patient with a 14-day hospital stay was the patient who required reoperation.

Table 1 Patient demographics

Patients	64
Gender: <i>n</i> (%)	
Women	49 (76.6)
Men	15 (23.4)
Mean age: years (range)	43 ± 10.4 (21–63)
Mean preoperative BMI: kg/m ² (range)	44.5 ± 4.9 (30.9–59)
Mean preoperative weight: kg (range)	121.6 ± 21.3 (80–191.7)

BMI body mass index

Table 2 Perioperative outcomes

Mean operative time: min (range)	238.1 ± 50.8 (150–400)
Intra-operative complications	0
Postoperative complications: <i>n</i> (%)	6 (9.4)
Grade 2	4 (66.6)
Pulmonary embolism	1
Deep venous thrombosis	1
Digestive hemorrhage	1
GJ edema	1
Grade 3b	1 (16.7)
Internal hernia	1
Grade 4a	1 (16.7)
Atelectasis	1
Mortality	0
Conversion	0
Reoperation: <i>n</i> (%)	1 (1.6)
Hospital stay: days (range)	6.5 ± 1.8 (3–14)

BMI body mass index; GJ gastrojejunostomy

Learning curve

The raw OT data were plotted in chronological case order (Fig. 1). The CUSUM learning curve is shown in Fig. 2. This curve was observed to consist of two different phases: phase 1 (the initial 14 cases) and phase 2 (the last 50 cases).

A comparison of various parameters between those two phases identified by CUSUM analysis is summarized in Table 3. In terms of patient demographics, no statistical difference was observed between the two phases, but a significant reduction in OT was observed between phase 1 (288.9 min) and phase 2 (223.6 min; $P = 0.0001$). However, another peak occurred between cases 40 and 43 with an increase in OT. This can be explained by a higher number of challenging cases that were managed (75% of males). In addition, minute per BMI decreased between phases 1 and 2 (6.6 vs. 5.1; $P = 0.0002$).

In terms of postoperative outcomes, the two groups did not differ statistically. The hospital stay showed a clinical difference between the phases 1 and 2 (7.1 vs. 6.3 days), but the difference did not reach statistical significance ($P = 0.14$).

Discussion

Robot-assisted RYGBP can be performed safely and effectively for morbidly obese patients even during the initial learning curve. Yet, the gastrojejunostomy is one of the most technically challenging portions of a laparoscopic RYGBP, requiring the use of advanced laparoscopic skills such as intracorporeal knot tying and suturing [2, 3] in an area difficult to reach. As mentioned by Yu et al. [2], a morbidly obese abdomen makes these tasks even more difficult, notably because of a thick abdominal wall resulting in increased abdominal wall torque and surgeon fatigue. These facts can explain the steep learning curve associated with laparoscopic RYGBP, reported to require 75–100 cases [4–7].

The introduction of robotics in the bariatric armamentarium in the early 2000s has brought new technical possibilities for overcoming the limitations of standard laparoscopy. However, to date, few series have reported the learning curve associated with robotic RYGBP [2–4, 12, 17, 18]. Moreover, to the best of our knowledge, none of them have used CUSUM analysis.

To date, studies investigating the learning curve for robotic RYGBP have performed their analysis based on chronological cases split into predefined segments, with univariate analysis performed to compare means across segments [2, 17]. For example, Yu et al. [2] split their 100 first cases of robot-assisted RYGBP into segments of 20 patients. They found that OT decreased throughout the

Fig. 1 Learning curve: operative time in minutes plotted against case number (n)

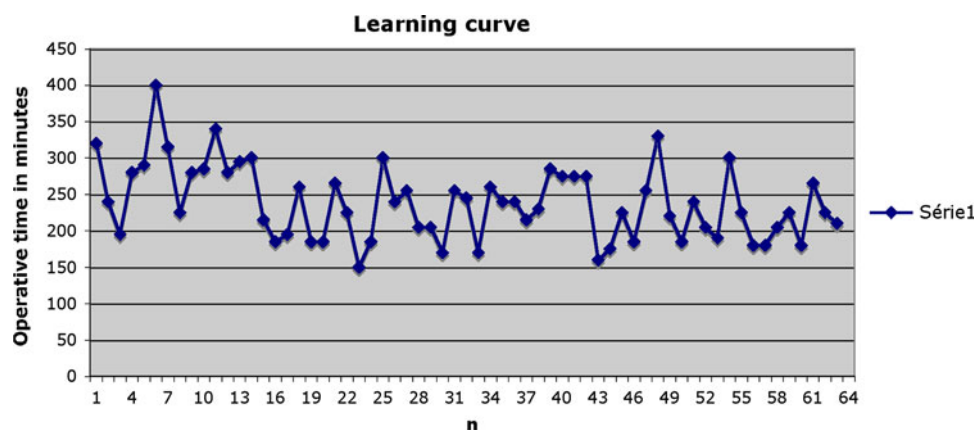


Fig. 2 Cumulative sum for operative time (CUSUM OT) plotted against case number. OT operative time

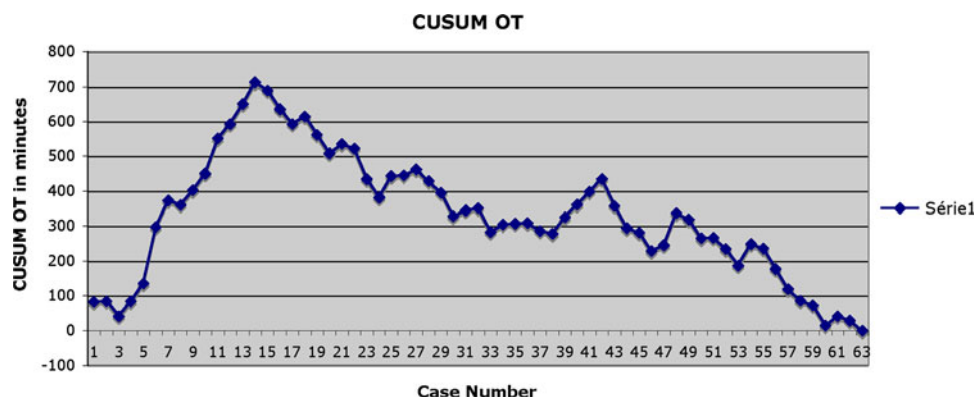


Table 3 Comparison between phases of patient characteristics and perioperative outcomes

	Phase 1 ($n = 14$)	Phase 2 ($n = 50$)	P value
Male:female ratio	4:10	11:39	0.72
Age (years)	43 ± 10.5	43 ± 10.5	1
Preoperative BMI (kg/m^2)	44.3 ± 4.4	44.6 ± 5	0.84
Preoperative weight (kg)	123.5 ± 19.3	121.1 ± 22	0.75
Operative time (min)	288.9 ± 49.9	223.6 ± 41.1	0.0001
Minute/BMI	6.6 ± 1.7	5.1 ± 1.1	0.0002
Intraoperative complications	0	0	1
Postoperative complications	2	4	0.6
Mortality	0	0	1
Conversion	0	0	1
Reoperation	0	1	1
Hospital stay (days)	7.1 ± 1.2	6.3 ± 1.9	0.14

Values are expressed as mean \pm standard deviation

BMI body mass index

series from approximately 275 min for the 20 first cases to 225 min for the last 20 patients. More recently, Ayloo et al. [12] found that 30 robotic cases were necessary for the

procedure to be performed in less time than required for the laparoscopic approach (202 vs. 227 min; $P = 0.047$). Similar findings were reported by others [17, 18].

In the robotic field, Bokhari et al. [14] were among the first to report the use of CUSUM analysis to evaluate the learning curve for colorectal resections. They found that the learning curve was achieved after 15–25 cases.

Thus, our study used the CUSUM method to evaluate the learning curve for robot-assisted RYGBP performed by a single surgeon already experienced in advanced laparoscopic procedures but with a limited experience in laparoscopic RYGBP. This study demonstrated the feasibility and safety of performing robot-assisted RYGBP even after a limited experience with laparoscopic bariatric procedures. However, a strong mentoring still is necessary to achieve good results.

We started the study after 50 cases of mentoring with the surgeon working as patient-side surgeon first. Interestingly, the concept that advanced surgical training can eliminate or at least reduce the learning curve often associated with complex minimally invasive procedures, specifically laparoscopic RYGBP, has been demonstrated recently by others [19]. Finally, it could be argued that the good outcomes reported in this article partly reflect the strong mentoring and the previous laparoscopic experience.

Undeniably, these facts may have an impact on the learning curve as well.

A higher complication rate is expected during a surgeon's learning curve [20]. The most dreaded complication associated with RYGBP remains anastomotic leak. The leak rate can be as high as 7% during the initial learning curve for laparoscopic RYGBP [7]. In our robotic series, we have had no leaks, and similar results have been reported by others [2, 3, 12, 17].

When comparing our 14 initial cases with the last 50 cases, we did not notice any statistical difference in terms of morbidity (14.3% vs. 8%; $P = 0.6$). However, a trend can be suspected from a clinical point of view. In addition, longer OT is expected during the learning curve as well. We confirmed these facts with a statistical difference between the two phases (288.9 vs. 223.6 min; $P = 0.0001$). Our results are well within the range of those reported in the most recent literature (130.8–254 min) [2, 3, 12, 13, 17]. Moreover, like Sanchez et al. [3], we used the minutes per BMI as a standardization of OT adjusted for the patient's BMI. We found a significant decrease in this value between phases 1 and 2.

Phase 1, found to require 14 cases, can represent the initial learning curve phase. Phase 2 can represent the mastery phase, with a reduction in OT. The increased OT in phase 2 (between cases 40 and 43) was attributed to a greater proportion of more technically demanding cases (male patients). Similar facts were reported by Bokhari et al. [14] for robotic colorectal resections.

To our knowledge, this is the first series to evaluate the learning curve of robot-assisted RYGBP using a CUSUM method. However, it has some limitations that deserve comment. First, no comparison was performed between the laparoscopic and robotic approaches. Sanchez et al. [3] performed this comparison with 50 randomized patients. These authors reported a shorter OT with the use of a robotic system during the surgeon's learning curve, and that decrease was maximized in patients with a large BMI. Similar findings were published recently by Ayloo et al. [12].

As stated earlier, previous laparoscopic experience and mentoring might have an impact on the learning curve as well. Probably, these facts associated with the robotic technology contribute to this short learning curve and the overall good outcomes.

Finally, the cost of a robotic approach was not analyzed. However, like Sanchez et al. [3], we strongly think that robotic surgery may increase the number of bariatric surgeons who will be able to provide the benefits of minimally invasive surgery to their patients without an increased risk of complications associated with the initial learning curve. The efficiency behind this concept is obvious, and the cost should be contained by limiting the morbidity rate.

However, it remains mainly hypothetical, and further studies still are required for firm conclusions to be drawn.

Conclusions

This study using CUSUM analysis identified two distinct phases of the learning curve in the field of robotic RYGBP. The data reported here suggest that the initial learning phase for robot-assisted RYGBP can be achieved after 14 cases. This series confirms previous study concerning the feasibility and safety of a robotic approach for RYGBP, even after a limited experience with laparoscopic RYGBP.

Disclosures Monika E. Hagen is a part-time consultant for Intuitive Surgical Inc. Nicolas C. Buchs, François Pugin, Pascal Bucher, Gilles Chassot, Pascale Koutny-Fong, and Philippe Morel have no conflicts of interest or financial ties to disclose.

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